Serial No. 08/379,872 Examining Group 1205

cient

--15. The method of claim 13, wherein said cancer is adrenal cancer.--

REMARKS

Upon entry of the present amendment, claims 1, 3-4 and 9-15 will remain pending in the above-identified application.

The above amendments do not incorporate new matter into the application as originally filed. Claim 13 is identical to claim 1, but is limited to gossypol, anti-cancer effective metabolites thereof, or physiologically effective salts thereof. Claims 14-15 are based on claims 3-4.

Restriction Requirement

In the outstanding Office Action, the Examiner required restriction under 35 USC § 121 to one of two allegedly distinct inventions. In response to the Restriction Requirement, the Applicants elect to prosecute, with traverse, the invention of Group I (claims 1 and 3-4). Further, Applicants elect the compound "gossypol" as a specific compound encompassed by the claimed invention for purposes of instituting a search. It is noted that newly added claims 13-15 read on the elected invention as well as the specific compound that was elected for searching purposes.

Enclosed 37 CFR § 1.132 Declaration

Enclosed with the present Amendment is a 37 CFR § 1.132 Declaration of Dr. Marcus M. Reidenberg, one of the present inventors. The Examiner is respectfully requested to review Dr. Reidenberg's Declaration at this time.

In Dr. Reidenberg's Declaration, he makes clear that gossypol acetic acid is a loosely bound complex of gossypol with acetic acid, and that other analogous complexes of gossypol have been formed with formic, propionic and butyric acids. Dr. Reidenberg further clarifies that the loose complex of gossypol with acetic acid is easily dissociated into its component parts of gossypol and acetic acid, and that it is the gossypol moiety itself that is responsible for the antineoplastic activity that has been observed and demonstrated in the present inventors' studies with gossypol acetic acid. As evidence of this anti-neoplastic activity, he supplies a copy of a 37 CFR § 1.132 Declaration of Mary R. Flack (dated February 12, 1992), which was filed on April 8, 1992, in the matter of parent U.S. Application Serial No. 07/551,353, now U.S. 5,385,936.

Upon properly considering the accompanying 37 CFR § 1.132 Declaration of Dr. Reidenberg, the Examiner will understand that the elected inventive method possesses an advantageous and unexpected effect in the treatment of various cancers. Moreover, the Declaration makes clear that the inventive discovery should not be limited to using the compound "gossypol" in the claimed method,

Serial No. 08/379,872 Examining Group 1205

since the anti-cancer effective metabolites of gossypol and the physiologically acceptable salts thereof, are also effective as anti-cancer agents in the inventive method. This is because gossypol forms loose complexes that are easily dissociated, with the anti-neoplastic activities that are possessed by the loose gossypol complexes resulting from the presence of a gossypol moiety in the complex. Exemplary of such loose gossypol complexes are ones formed by gossypol with acetic acid, formic acid, propionic acid and butyric acid.

CONCLUSION

Should the Examiner have any questions regarding this matter, he is respectfully requested to contact Mr. John W. Bailey (Reg. No. 32,881), who may be reached in the Washington, DC, area at (703) 205-8000.

Please charge any fees or credit any overpayment pursuant to 37 CFR § 1.16 and 1.17 to Deposit Account No. 02-2448.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Gerald M. Murphy, Req. No. 28,977

PO Box 747

Falls Church, VA 22040-0747

(703) 205-8000

GMM/JWB:las 1173-485P